MAR 17 2000

K000286

SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is being submitted in accordance with the requirements of The Safe Medical Devices Act of 1990 (SMDA 1990) and 21 CFR 807.92.

I. GENERAL INFORMATION

Date of Summary Preparation: January 27, 2000

Distributor:
BRAHMS Diagnostica, LLC
29 South Peachtree Street
Norcross, Georgia 30092

Manufacturer:
BRAHMS Diagnostica, GmbH
Neuendorfstrasse 25
D-16761 Hennigsdorf
Germany

Contact Person:
H. Lee Herron
Partner
BRAHMS Diagnostica, LLC
29 South Peachtree Street
Norcross, Georgia 30092
Tel: 770-449-7738
Fax: 770-449-7739

Device Name: LUMItest® anti-Tg_n

Common or Usual Name: Luminescence immunoassay kit for the determination of anti-thyroglobulin antibodies

Classification:

Name:	Thyroid autoantibody immunological test system
Class	Class II
CFR:	21 CFR 866.5870

Substantial Equivalence To: DYNOtest® anti-Tg_n

II. INTENDED USE

LUMItest anti-Tg_n is a competitive luminescence immunoassay (LIA) for the quantitative determination of autoantibodies against thyroglobulin (Tg) in human serum using the coated tube technique. The LUMItest anti-Tg_n kit is used as an aid in the diagnosis of Hashimoto's thyroiditis and Graves' disease, autoimmune diseases affecting the thyroid gland.

III. DEVICE DESCRIPTION

LUMItest anti-Tg_n is a competitive luminescence immunoassay intended for the quantitative determination of autoantibodies against thyroglobulin in human sera using a coated tube technique. Human polyclonal antibodies against thyroglobulin bound to the solid phase compete with autoimmune ant-thyroglobulin antibodies in the sample for acridinium ester-labeled thyroglobulin. Following incubation, unreacted labeled thyroglobulin is washed from the tube and luminescence bound to the tube is counted. The measured luminescence is inversely proportional to the quantity of anti-thyroglobulin antibody in the sample.

IV. COMPARISON TO PREDICATE DEVICE

The LUMItest® anti-Tg_n immunoassay kit is similar to the DYNOtest® anti-Tg_n (K992790) in the indications for use, format, performance characteristics and results. The LUMItest anti-Tg_n test differs from DYNOtest anti-Tg_n only in the signal used to detect outcome of the test. In the LUMItest anti-Tg_n assay, a luminogenic molecule, acridinium ester, is used to replace the ^{125}I signal used in the DYNOtest anti-Tg_n assay.

Substantial equivalence to the DYNOtest anti-Tg_n kit cleared under K992790 is based on clinical comparison using 503 serum samples from normal blood donors (n=300) and patients with Graves' disease, Hashimoto's thyroiditis and non-autoimmune thyroid disease (n=203). Overall agreement of both groups based on a 2 X 2 agreement table was 501/503= 99.6%.

		DYNOtest anti-Tg	
LUMItest Anti-Tg		Positive	Negative
	Positive	144	0
	Negative	2	357

% Agreement = 99.6%

This correlation study demonstrates that the LUMItest anti-Tg_n assay is substantially equivalent to the legally marketed predicate device, DYNOtest anti-Tg_n assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 17 2000

Mr. H. Lee Herron
Partner
BRAHMS Diagnostica, LLC
29 South Peachtree Street
Norcross, Georgia 30092

Re: K000286
Trade Name: LUMItest® anti-Tg_n
Regulatory Class: II
Product Code: JZO
Dated: January 28, 2000
Received: January 31, 2000

Dear Mr. Herron:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

1. Indications for Use Statement

510(k) Number (if known): K000286
Device Name: LUMItest anti-Tg_n

Indications For Use:

LUMItest anti-Tg_n is a competitive luminescence immunoassay (LIA) for the quantitative determination of autoantibodies against thyroglobulin (Tg) in human serum using the coated tube technique. The LUMItest anti-Tg_n kit is used as an aid in the diagnosis of Hashimoto's thyroiditis and Graves' disease, autoimmune diseases affecting the thyroid gland.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maker

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K000286

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)